REGISTRATION REPORT

Part A

Risk Management

Product code: MADEX TWIN JARDIN

Active Substance(s):

***Cydia pomonella* Granulovirus isolate V22 (CpGV),**

2×10^{12} OB/L (96.25 g/L)

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: Andermatt Biocontrol AG

Date: 13/06/2019

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PART A – Risk Management

The company Andermatt Biocontrol GmbH has requested a marketing authorisation in France for the product MADEX TWIN JARDIN, containing 96,25 g/L (2 x 10^{12} OB/L) *Cydia pomonella* Ganulovirus isolate V22 for use as an insecticide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to MADEX TWIN JARDIN where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of MADEX TWIN JARDIN have been made using endpoints agreed in the EU peer review(s) of *Cydia pomonella* Granulovirus isolate V22.

This document describes the specific conditions of use and labelling required for France for the registration of MADEX TWIN JARDIN.

Appendix 1 of this document provides a copy of the French Decision.

Appendix 2 of this document is a copy of the draft product label as proposed by the applicant.

Appendix 3 of this document is a copy of the letter(s) of Access.

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of Andermatt Biocontrol AG's application to market MADEX TWIN JARDIN in France as an insecticide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

***Cydia pomonella* Granulovirus**

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Specific provisions of Regulation (EU) No 540/2011 were as follows : PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on *Cydia pomonella Granulovirus* (CpGV) (SANCO/1548/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.
An EFSA conclusion is available (EFSA Journal 2012; 10(4): 2655). A Review Report is available (SANCO/1548/08 rev. final, 13 July 2012. Rev.5 11 July 2014).

1.3 Regulatory approach

The present application (2017-1440) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[1] – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

According to the French law and procedures, specific conditions of use are set out in the Decision letter.

The French Order of 4th May 2017[2] provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, drift buffer zones may be reduced under some circumstances as explained in Appendix 3 of the above-mentioned French Order.

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[3], implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[5] provides that:
- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[6] is to supply "minor" crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national

[1] SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

[2] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

[3] REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

[4] COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

[5] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

[6] SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

mitigation measures.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of MADEX TWIN JARDIN, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

The applicant is part of the task force owning the active substance and letter of access has been provided.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	MADEX TWIN JARDIN
Authorisation number	N/A : no marketing authorisation granted
Function	Insecticide
Applicant	Andermatt Biocontrol AG
Composition	96,25 g/L (2 x 10^{12} OB/L) *Cydia pomonella* Granulovirus isolate V22
Formulation type (code)	Suspension concentrate (SC)

2.2 Classification and labelling

2.2.1 Classification and labelling in accordance with Regulation (EC) No1272/2008

Physical hazards	none	
Health hazards	none	
Environmental hazards	none	
Hazard pictograms	-	
Signal word	none	
Hazard statements	none	
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)		

See Part C for justifications of the classification and labelling proposals.

2.2.2 Other phrases in compliance with Regulation (EU) No 547/2011

N/A : no marketing authorisation granted

2.2.3 Other phrases linked to the preparation

N/A : no marketing authorisation granted in France

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP rev. 2019/06/13

PPP (product name/code):	**MADEX TWIN JARDIN**	Formulation type:	**SC** [a, b]
Active substance 1:	Cydia pomonella Granulovirus isolate V22	Conc. of as 1:	**2×10^{12} OB/L (96.25 g/L)** [c]
Safener:	n.c	Conc. of safener:	n.c [c]
Synergist:	n.c	Conc. of synergist:	n.c [c]
Applicant:	Andermatt Biocontrol AG	Professional use:	☐
Zone(s):	Southern	Non professional use:	☒
Verified by MS:	yes		
Field of use:	Insecticide.		

Crop and/ or situation (a)	**Zone**	**Product code**	**F G or I (b)**	**Pests or Group of pests controlled (c)**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days) (l)**	**Remarks: (m) RMS Conclusion**
					Type (d-f)	**Conc. of MCPA (i)**	**method kind (f-h)**	**growth stage & season (j)**	**Max. number a) per use b) per crop/ season (k)**	**interval between applications (min)**	**MCPA /hL min max**	**water L/ha min max**	**Granules MCPA/ ha min max**		

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m) RMS Conclusion
					Type (d-f)	Conc. of MCPA (i)	method kind (f-h)	growth stage & season (j)	Max. number a) per use b) per crop/ season (k)	interval between applications (min)	MCPA /hL min max	water L/ha min max	Granules MCPA/ ha min max		
Pome fruits (apple, pear, quince, Nashi, *Mespilus*)	France	Madex ® Twin Jardin	HG[2] (field)	*Cydia pomonella* *Grapholita molesta*	SC	2 x 10^{12} granules/ L	Spraying Knapsack sprayer	Before first larvae hatch from eggs[3)]	a) 9 b) 12	6-8 sunny days (2 partially sunny days = 1 sunny day)	1.875 x 10^{11} - 3.75 x 10^{11} granules /hL	8 L/100 m^2	1.5 x 10^{12} - 3 x 10^{12} granules /ha (7.5-15 ml/100 m^2)	Not necessary	**Not acceptable** (contaminant microbial analysis missing, risk for non-professional user)
Walnut	France	Madex ® Twin Jardin	HG[2)] (field)	*Cydia pomonella*	SC	2 x 10^{12} granules/ L	Spraying Knapsack sprayer	Before first larvae hatch from eggs[3)]	a) 9 b) 9	6-8 sunny days (2 partially sunny days = 1 sunny day)	1.875 x 10^{11} - 3.75 x 10^{11} granules /hL	8 L/100 m^2	1.5 x 10^{12} - 3 x 10^{12} granules /ha (7.5-15 ml/100 m^2)	Not necessary	**Not acceptable** (contaminant microbial analysis missing, risk for non-professional user)

Crop and/ or situation (a)	**Zone**	**Product code**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)** (l)	**Remarks:** (m) **RMS Conclusion**
					Type (d-f)	**Conc. of MCPA** (i)	**method kind** (f-h)	**growth stage & season** (j)	**Max. number** a) per use b) per crop/ season (k)	**interval between applications (min)**	**MCPA /hL** min max	**water L/ha** min max	**Granules MCPA/ ha** min max		
Stone fruits (apricot, peach, nectarine, plum)	France	Madex ® Twin Jardin	HG[2)] (field)	*Grapholita molesta*	SC	2 x 10^{12} granules/ L	Spraying Knapsack sprayer	Before first larvae hatch from eggs[3)]	a) 12 b) 12	6-8 sunny days (2 partially sunny days = 1 sunny day)	1.875 x 10^{11} - 3.75 x 10^{11} granules /hL	8 L/100 m^2	1.5 x 10^{12} - 3 x 10^{12} granules /ha (7.5-15 ml/100 m^2)	Not necessary	**Not acceptable** (contaminant microbial analysis missing, risk for non-professional user
Almond	France	Madex ® Twin Jardin	HG[2)] (field)	*Grapholita molesta*	SC	2 x 10^{12} granules/ L	Spraying Knapsack sprayer	Before first larvae hatch from eggs[3)]	a) 12 b) 12	6-8 sunny days (2 partially sunny days = 1 sunny day)	1.875 x 10^{11} - 3.75 x 10^{11} granules /hL	8 L/100 m^2	1.5 x 10^{12} - 3 x 10^{12} granules /ha (7.5-15 ml/100 m^2)	Not necessary	**Not acceptable** (contaminant microbial analysis missing, risk for non-professional user

(2) = Home garden use

Remarks: (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

3 RISK MANAGEMENT

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

MADEX TWIN JARDIN is a Suspension concentrate. All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a grey-brown liquid, without odour. It is not explosive and has no oxidising properties. The product is not flammable and no flash point was observed up to 101 °C. It is not auto-flammable. In aqueous solution (1%), it has a pH value of 6.4 at 20.1°C. The product is stable for 1 week at 0°C in PET packaging; the technical properties were not changed.

A new study on shelf life (24 months at 5 °C) on the preparation MADEX TWIN (same as MADEX TWIN JARDIN but more concentrate) in PET packaging was provided and considered acceptable and can be extrapolated to MADEX TWIN JARDIN for bioactivity for physical and chemical properties. **.** Its technical characteristics are acceptable for an SC formulation.

Nevertheless, data provided are insufficient to allow the determination of microbial contaminants including *Bacillus cereus* before and after 2-year storage at 5 °C in the product MADEX TWIN JARDIN, according to approval conditions of *Cydia pomonella* GV.

The formulation is not classified for the physical and chemical aspect.
The formulation must be stored between 0 °C and 5°C and not be stored more than 2 years.
The formulation must be shaken during the application.
The product should be protecting from the light.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical method for the determination of the microbial active substance in the formulation is available and validated.
Analytical methods for the determination of microbial contaminants according to OECD 65 are available and validated.

3.1.2.2 Analytical methods for residues

Analytical methods for the determination of residues are not necessary as no residue definition.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

Active substance	**ADI** mg/kg.bw/d	**ArfD** mg/kg.bw	**AOEL** mg/kg.bw/d	**Classification**
Cydia pomonella Granulovirus isolate V22	Not relevant for microorganisms			Micro-organisms may have the potential to provoke sensitising reactions.

The derivation or reference values were not needed based on the absence of toxicity, infectivity and pathogenicity indications of the micro-organism.

3.1.3.1 Acute Toxicity

MADEX TWIN JARDIN containing 2 x 10^{12} OB/L (96.25 g/L) *Cydia pomonella* Granulovirus isolate V22 has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye.
The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.

3.1.3.2 Operator Exposure

The French study 2005 dedicated to amateur use is not suitable for calculating a risk assessment for operators on the base of a not existing dose-effect relation.
The preparation is considered safe for operators based on the low toxicity profile and the application.

The proposed packaging has been described in sufficient detail, and its compliance can therefore be finalised.
In summary, lack of compliance with the provisions of French Decree No. 2010-1755 of 30 December 2010 and Orders of 30 December 2010 relating to the use of certain plant protection products by non-professional users is considered to be not acceptable for the proposed packaging (bottle with simple cap).

3.1.3.3 Bystander Exposure

Following the above given reasons for abstaining from an estimation of operator risk assessment, this also applies with regard to bystanders and residents. As regard the application method, bystander and residential exposure is supposed to be negligible for field uses.

3.1.3.4 Worker Exposure

MADEX TWIN JARDIN is intended to be used by amateurs during home garden application. In this case of the non-professional user, the worker is also the user of the product. The micro-organism is neither toxic or infectious or pathogenic in mammals, it is not expected an unacceptable risk for the worker.
For details of personal protective equipment for workers, refer to the Decision in Appendix 1.

3.1.4 Residues and Consumer Exposure

The intended uses of *Cydia pomonella* Granulovirus (*Cydia pomonella* GV) do not represent a risk for the consumer.

Indeed, viruses including *Cydia pomonella* GV are not able to produce antimicrobial substances, toxins or secondary metabolites and are not sensitive to antibiotics. Furthermore baculoviruses, especially granuloviruses, have a narrow host range and are strictly host-specific to certain arthropod species.
Additionaly toxicity studies performed with *Cydia pomonella* GV or others baculoviruses shown no adverse effects. Consequently based on the toxicity studies and considering the lack of pathogenicity of the baculoviruses in mammals it was concluded at EU level (EFSA, 2012) that the setting of dietary toxicological values were not required, and therefore that a quantitative risk assessment was not necessary for *Cydia pomonella* Granulovirus, then *Cydia pomonella* Granulovirus was included in Annex IV of Regulation (EC) No 396/2005.

The annex IV includes substances for which no MRL are required and therefore it is considered that the risk of residue on pome fruits, walnuts, almond and stone fruits can be considered as negligible. Therefore, a PHI should not be necessary depending on national requirement.

In the preparation MADEX TWIN JARDIN, contamination with *Bacillus cereus* was within the acceptable limits established in food products of plant ($<10^7$ CFU/g).

Consequently it can be concluded that the intended uses of MADEX TWIN JARDIN do not represent a risk for the consumer.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate PECs for the active substance for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.
The PEC of the active substance in soil, and surface water have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions (EFSA, 2012).

PEC soil and PECsw derived for the active substance are used for the ecotoxicological risk assessment. No unacceptable risk of groundwater contamination is expected for the intended uses.

3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation MADEX TWIN JARDIN was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate, such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, aquatic organisms, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses.

3.1.7 Efficacy

Considering the data submitted:

- the efficacy level of MADEX TWIN JARDIN is considered as acceptable for all the claimed uses.
- the phytotoxicity level of MADEX TWIN JARDIN is considered as negligible for all the claimed uses.
- the risk of negative impact on adjacent crops is considered as negligible.
- the risk of development resistance or appearance to CpGV-V22 isolate used in home garden should not be increased in comparison with the professional uses.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation cannot be granted. A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision. **The claimed packaging does not guarantee a minimum exposure of the non-professional user.**

3.3 Substances of concern for national monitoring

No information stated.

3.4 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

3.4.1 Post-authorisation monitoring

N/A : not registered in France

3.4.2 Post-authorisation data requirements

N/A : not registered in France

3.4.3 Label amendments

The draft label proposed by the applicant in appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label shall reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French Decision

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anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et règlementaire,

Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique ***MADEX TWIN JARDIN***

de la société	*ANDERMATT BIOCONTROL GmbH*
enregistrée sous le	*n°2017-1440*

Vu les conclusions de l'évaluation de l'Anses du 3 mai 2019,

Considérant que l'amplification de la contamination ne peut être exclue, en l'absence d'analyse des contaminants microbiens après stockage,

Considérant également que les emballages du produit ne permettent pas de garantir une exposition minimale de l'utilisateur non professionnel, conformément à l'article 1 de l'arrêté du 30 décembre 2010,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.

MADEX TWIN JARDIN
AMM n°-

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Informations générales sur le produit	
Nom du produit	MADEX TWIN JARDIN
Type de produit	Produit de référence
Titulaire	ANDERMATT BIOCONTROL GmbH Zellerstrasse 9, 79618 RHEINFELDEN Allemagne
Formulation	Suspension concentrée (SC)
Contenant	2.10^{12} OB/L - *Cydia pomonella* Granulovirus (isolat CpGV-V22)
Numéro d'intrant	473-2017.01
Numéro d'AMM	-
Fonction	Insecticide
Gamme d'usage	Amateur / emploi autorisé dans les jardins

A Maisons-Alfort le, 13 JUIN 2019

Caroline SEMAILLE
Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

MADEX TWIN JARDIN
AMM n°-

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Appendix 2 – Copy of the draft product label as proposed by the applicant

MADEX TWIN JARDIN

Insecticide biologique
Virus de la granulose de *Cydia pomonella*, isolat V22 : 2 x 10^{12} corps viraux/l.
Traitement des parties aériennes Pêchers, Abricotiers, Amandiers, Noyers, Pommiers, Poiriers, Cognassier, Nashi, Prunier contre les chenilles foreuses des fruits : *Cydia pomonella* et *Grapholita molesta* : **7.5 - 15 ml/ 100 m²**.
Formulation : suspension concentrée (SC).
AMM N° - xxxxxx
Andermatt Biocontrol GMBH-Zellerstrasse 9, 79618 Rheinfelden (Allemagne).
Produit utilisable en Agriculture Biologique conformément au règlement (CE) N°834/2007.

100 ml.

Utilisez les produits phytosanitaires avec précaution. Avant toute utilisation, lisez l'étiquette et les informations concernant le produit.

Préparation fabriquée par : Andermatt Biocontrol S.A., Suisse
Préparation commercialisée par : **Andermatt France** Cré@ticité Bat A – Technopole Izarbel – 64210 Bidart - Tél. : 05 64 11 51 04 contact@andermatt.fr. ® est une marque déposée - Andermatt Biocontrol AG.

Numéro de lot et date de production : voir indication sur le bouchon

Recommandation d'emploi : Madex Twin Jardin est efficace sur les jeunes larves du carpocapse et tordeuse orientale du pêcher. Madex Twin Jardin peut être appliqué 9 fois par an contre carpocapse des pommes et des poires et 12 fois par an contre tordeuse orientale du pêcher.

Délai avant récolte : 1 jour. DRE : 6 heures. Zone Non Traitée : 5 mètres.
Ne pas traiter durant toute la période de floraison et pendant la période de production des exsudats, en dehors de la présence des abeilles.

Préparation de la bouillie
Respecter les conseils de prudence. Remplir la cuve à moitié d'eau, verser directement **Madex® Twin Jardin puis**, compléter le volume de bouillie. Maintenir une agitation efficace pendant la préparation.
Après l'utilisation, rincer et nettoyer les appareils soigneusement avec de l'eau conformément à la réglementation en vigueur. Effectuez une pulvérisation homogène avec un volume de bouillie suffisant pour mouiller les feuilles, rameaux et fruits.

Volume de bouillie appliqué

Il est essentiel d'effectuer une pulvérisation homogène avec un volume de bouillie suffisant pour mouiller les feuilles, rameaux et fruits sans provoquer la formation de grosses gouttelettes ou le ruissellement.

Compatibilité : Respecter la législation en vigueur. Ne pas mélanger **Madex® Twin Jardin** avec tout produit pouvant conduire à un pH dans la cuve inférieur à 5 ou supérieur à 8,5 ainsi qu'avec tout produit contenant du cuivre.

Stockage : Ce produit, d'origine biologique, est sensible aux conditions de stockage. Stocké dans son emballage d'origine fermé, au froid (réfrigérateur ou chambre froide spécifiques) à 5°C, cette préparation se conserve pendant 2 ans.

IMPORTANT : Conduisez sur ces bases la culture et les traitements selon la bonne pratique agricole en tenant compte sous votre responsabilité de tout facteur particulier concernant votre exploitation tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces. Le fabricant garantit la qualité des produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de mise en marché du Ministère chargé de l'Agriculture.

Premiers soins
En cas d'inhalation (ceci n'est possible que par exposition à un produit chaud), passer à l'air frais, se reposer, en position à-demi verticale, desserrer les vêtements. Oxygène ou respiration artificielle en cas de difficulté de respiration. Consulter un médecin après une exposition importante. Le traitement symptomatique est conseillé. En cas de contact avec la peau : Retirer les vêtements contaminés. Consulter un médecin en cas d'irritation. Mettre les vêtements à la blanchisserie avant réutilisation. Après un contact avec la peau, laver immédiatement et abondamment à l'eau.
En cas de contact avec les yeux : Rincer abondamment à l'eau. Soulever les paupières du globe oculaire pour assurer le rinçage en profondeur. Consulter un médecin en cas d'irritation. En cas d'ingestion : Pas de symptômes ni d'effets typiques connus. Consulter un médecin.

Madex Twin Jardin - Classement
Contient du *granulovirus* de *Cydia pomonella*. Peut entraîner une réaction de sensibilisation

Phr Risque : SANS CLASSEMENT

Phr Prudence / VOIR ARRETES APPROPRIES SUR LE CLASSEMENT ET L'ETIQUETAGE POUR LS CONSEILS DE PRUDENCE.

Conseils de prudence

Contient du granulovirus de Cydia pomonella. Peut entraîner une réaction de sensibilisation.
P101 En cas de consultation d'un médecin, garder à disposition le récipient ou l'étiquette.
P102 Tenir hors de portée des enfants.
P261 Éviter de respirer les vapeurs.
P270 Ne pas manger, boire ou fumer en manipulant le produit.
EUH401 Respecter les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.
SP1 Ne pas polluer l'eau avec le produit ou son emballage. (Ne pas nettoyer le matériel d'application près des eaux de surface. Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes).
SPe 3 Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 m par rapport aux points d'eau.
Délai de rentrée dans la culture pour les travailleurs : 6 h.

Ne pas réutiliser l'emballage vide. Lors de l'utilisation du produit, bien vider et rincer le bidon en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Éliminer les emballages vides via un système de collecte spécifique. Réemploi de l'emballage interdit. Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.

En cas d'urgence, appeler le 15 ou le centre anti-poison, puis signaler vos symptômes au réseau Phyt'attitude : *N° Vert 0 800 887 887* (appel gratuit depuis un poste fixe). Fiche de données de sécurité disponible sur simple demande.

Appendix 3 – Letter(s) of Access

Letter(s) of access and, if necessary, an argumentation according to art. 62.4 of Reg (UE) No 1107/2009 have been submitted and are available under request.